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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/622,439	08/17/00	MATSUMOTO	M 060438

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HM12/1023

EXAMINER

WEGERT, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/23/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/622,439	MATSUMOTO ET AL.
	Examiner Sandra Wegert	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 25 July 2001.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-30 is/are pending in the application.
  - 4a) Of the above claim(s) 1,2,7 and 8 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3-6 and 9-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 25 July 2001 is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Status of Application, Amendments, And/Or Claims***

The amendment filed 5 June 2001 (Paper No. 10) has been entered. The substitute Specification as well as the response and amendment, filed 7/25/01 (Paper No. 11) have been entered in full. Claims 9-30 were added. Claims 1, 2, 7, and 8 are drawn to non-elected inventions. Claims 3-6, and 9-30 are under examination.

The proposed drawing corrections, received on 27 July 2001 have been approved by the examiner. Formal drawings will be expected to reflect the proposed alterations.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The objection to the disclosure for informalities as set forth at pp. 2-3 of the previous Office Action (Paper No. 9, 25 April 2001) is *withdrawn* in view of the amendments correcting same (Paper No. 11, 25 July 2001).

The application is now fully in compliance with the sequence rules, 37 CFR 1.821-1.825.

The rejection of claims 3-6 under 37 CFR § 102(e) as being anticipated by Elshourbagy et al in US Patent 6,071,722 as set forth at pp. 7-8 of the previous Office Action (Paper No. 9, 25 April 2001) is *withdrawn*. This rejection is withdrawn in view of the English translation submitted (Paper 11, 25 July 2001) of Japanese Patent 10-060245, filed 12 March 1998, to which the instant application claims priority.

**Claim Rejections - 35 USC § 101 and 35 USC § 112--first paragraph, utility/enablement**

Claims 3-6 and 9-30 are rejected under 35 U.S.C. 101 and 112, first paragraph, as lacking utility and not being enabled for lack of utility. The reasons for this rejection are set forth at pp. 4-7 of the previous Office Action (Paper No. 9, 25 April 2001).

Applicant argues (pp. 6-10, Paper No. 11, 25 July 2001) that the specification discloses a G-protein coupled receptor, SREB2, that is involved in the process of long-term potentiation (LTP) in the hippocampus. Several experimental examples are described that purportedly impart function on SREB2: In one example, a cDNA probe is used to determine expression of SREB2 mRNA across several tissue types. In another example, commercially available reporter plasmids are used to investigate SREB interactions with the nuclear response elements CRE and SRE. The Applicant also cites experiments in which antibodies are used to identify SREB receptors. Applicant then discusses the mechanisms of long-term potentiation (LTP) and long-term depression (LTD) in the hippocampus, and make inferences about the function of CREB2 involvement in the process of LTP. Applicants conclude by pointing out that the Patent cited in the 35 USC § 102(e) rejection of the previous Office Action (El Shourbagy, et al, US 6,071,722) (Paper No. 9, 25 April 2001), demonstrates less utility than the currently claimed polynucleotide of SEQ ID NO: 3 of the Instant Application.

Applicant's arguments (pp. 6-10, Paper No. 11, 25 July 2001) have been fully considered but are not deemed to be persuasive for the following reasons:

To address the last issue: The rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have real (e.g., not "throw-away") utility. Additionally, each Patent Application is examined on its own merits. What was deemed allowable in one Patent has no bearing on this Application.

Applicant argues that SREB2 activation of CREB, as well as the Northern blots showing CREB2 expression in hippocampus, are evidence that SREB2 is involved in LTP. There are several problems

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with this argument. Firstly, many- perhaps the majority -of G-protein coupled receptors make use of CRE/CREB in their transduction cascades (White, et al, PNAS, 2000; Pende, et al, J. Neurosci, 1997; Sheriff, et al, JPET, 1997). Many also utilize the serum response element SRE (Mao, et al, JBC, 1998; Shi, et al, JBC, 2000; Fromm, et al, PNAS, 1997; Herman, et al, JBC, 1995; Morin, et al, Mol. Cell. Biol., 2001). G-protein coupled receptors appear to be *generalists* in their intracellular transduction cascades, and one would expect that an unknown receptor *would* likely cause binding and phosphorylation of CRE/CREB after receptor activation. Thus the Applicant's argument that CREB is important in long-term potentiation just points out the fact that CREB phosphorylation is important in numerous biological processes, LTP being one of them (White, et al, PNAS, 2000; Pende, et al, J. Neurosci, 1997; Sheriff, et al, JPET, 1997). Indeed, the examples cited in the Instant Application are evidence of the generality of third messengers and nuclear response elements, since the receptors SREB1, SREB2, and SREB3, used by the Applicant, *all* activated transduction pathways leading to activation of *both* CRE and SRE (Figs 11 and 12).

Applicant demonstrated through a Northern analysis that SREB2 is expressed in the hippocampus, and argues that this is evidence that SREB2 is involved in the processes of LTP or LTD. However, not only is SREB2 expressed in the hippocampus, it is expressed in almost every tissue of neural origin, as well as in testis. This argues against the receptor being specific for LTP and instead seems to indicate that the receptor is important for a more general process, such as housekeeping or responses to growth factors, or that the receptor is found on a widely distributed cell such as an astrocyte or macrophage. It should be noted that the document submitted with the amendment of 25 July 2001 (Paper 11) entitled "Isotopic In Situ Hybridization Study-MM1" is not officially of record, since it was not documented in a PTO form 1449 or submitted under a 37 CFR 1.132 affidavit.

### ***Conclusion***

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No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

10/11/01

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER